1. To what extent did the article focus

2. What regulatory body provides accreditation and oversight of provider compliance for glucose meters?

3. FDA guidance documents make a clear

4. The FDA’s purpose for creating the guidelines were due to adverse events and numerous deaths when

5. When the FDA was creating new guidance for manufacturers, what problems were identified with original guidelines about performance criteria?

6. Currently there is/are device(s) that is/are cleared and classified by the FDA as a blood glucose monitoring test system (BGMS) for prescription POCl use.

7. After the FDA clearance of the only glucose monitoring device, there was growing concern that the device did not include the use of

8. The only FDA cleared glucose monitoring device was not approved for use by CLIA-waived operators.

9. An OTC SMBG device used in a hospital setting is considered

10. Compliance with rules and regulations of an off-label glucose monitor poses regulatory and legal concerns for providers and patients.

11. When are glucose monitors considered high complexity testing?

12. When a hospital chooses to use an OTC SMBG, the hospital and labs must

13. Legal consequences can occur with the use of off-label glucose meters and the liability(ies) than can occur is/are

14. Tort liability can occur if

15. If informed consent is not provided to patients in regard to off-label use of glucose monitors, liability can occur under the theory of

16. Medical facilities are protected and are not directly liable for a patient’s injuries in the use of off-label glucose meters.

17. What departments of a healthcare institution should a lab work with in the use of off-label blood glucose monitors?

Tests can be taken online or by mail. Easy registration and payment options are available through NIU by following the links found at www.mlo-online.com/ce.